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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,401	05/12/2005	Filip Arnaut	VANM199.005APC	6305
20995 7590 09/30/2009 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER BADR, HAMID R	
			ART UNIT 1794	PAPER NUMBER
			NOTIFICATION DATE 09/30/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/510,401	<b>Applicant(s)</b> ARNAUT ET AL.	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on RCE, 8/12/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-18 and 23-32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 23-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/2009 has been entered.

Note: The Declaration under 37 C.F.R. 1.132, by Mr. Thierry Dauvrin, is acknowledged. This declaration has been reviewed thoroughly.

Claims 1-18, and 23-32 are being considered on the merits.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6-7, 9-10, 13-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Klingenberg et al. (DD 156,714 A; hereinafter R1).

3. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

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4. Although there is no explicit disclosure of preventing or retarding staling during the baking process of the bakery products, given that R1 discloses method and improver identical to that presently claimed, it is clear that the method and the improver would inherently prevent or retard staling during the baking process of the bakery products.

5. Given that the weakening of gluten is disclosed it is clear that the protease is added to the dough prior to baking as presently claimed.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-4, 8, 12, 17, 25, 27, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenberg et al. (DD 156,714 A; hereinafter R1) in view of Olesen et al. (US 6,110,508; hereinafter R2)

8. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

9. Given that the weakening of gluten is disclosed it is clear that the protease is added to the dough prior to baking as presently claimed.

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10. It is also noted that the addition of protease and other enzymes such as amylase in order to increase the shelf life of bread (retard staling) is an old and known process in the art.

11. Regarding claim 3, it is obvious that a thermostable enzyme with a high optimum temperature for activity will be much more active than the same enzyme at much lower temperature e.g. 25C. The property of a much higher activity of a thermostable enzyme at higher temperature compared to the activity of the same enzyme at lower temperature will be inherent in the enzyme.

R1 is silent regarding addition of other enzymes and emulsifier to the dough.

12. R2 discloses the use of lipase together with other enzymes such as cellulase, hemicellulase, xylanase, glucose oxidase, peroxidase, amyloglucosidase, and alpha-amylase in bakery products including bread (Col. 5, lines 33-46). Bacterial alpha-amylase is known in the art and is a thermostable enzyme. It would be obvious to those of skill in the art to select a thermostable amylase such as a bacterial amylase to add to the dough formulations.

20. R2 teaches using emulsifiers such as mono and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides (DATEM), sugar esters of fatty acids, lactic acid esters of monoglycerides, polyoxyethylene stearates, phospholipids and lecithin in their dough improver (Col. 6, lines 46-56). These emulsifiers are used to improve dough extensibility as well as the consistency and storage stability of the bread.

21. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a thermostable protease as taught by R1 and include the

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improving enzymes and emulsifiers taught by R2 to receive the benefits of the dough improving properties of such enzymes and emulsifiers to prevent or retard staling in baked goods. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

13. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1 in view of Terada et al. (US 5,124,261; hereinafter R3) and Chernoglazov et al. (RU 2,177,799; hereinafter R4).

14. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above. R1 is silent regarding protease of *Thermus aquaticus* and Keratinase of *Bacillus lecheniformis*.

15. R3 discloses a process for the production of aqualysin I employing a genetic engineering procedure by cultivation of *Thermus aquaticus* (Col. 1, lines 34-52 and Col. 8, lines 31-51).

16. R3 is silent regarding a keratinase enzyme.

17. R4 discloses a new keratinase from *Bacillus licheniformis*. The keratinase can be used in the food industry (Abstract).

16. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 by including the protease and keratinase taught by R3 and R4. One would do so to receive the benefits of a thermostable protease and keratinase at least at the early stages of baking where the

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temperature is high enough for the activation of these thermostable enzymes and yet not that high to denature such enzymes.. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

18. Claims 2, 5, 11, 23, 24, 26, and 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over R1 as applied above, further in view of Stetter (US 5,714,373; hereinafter R5).

19. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above.

20. R5 discloses the isolation and identification of a thermostable protease from *Thermococcus* which has an optimum temperature range between 60C and 90C (col.7, lines 38-41).

21. It would have been obvious to one of ordinary skill in the art to use proteases which have an optimum range of activity in the 60C-90C.

22. Claims 5 and 26 are obvious due to the fact that serine proteases have a serine residue at the active site which acts as a nucleophilic residue in proteolytic activities, being active at neutral or alkaline pH.

23. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ the thermostable proteases from various sources as taught by R1, R3, R4 and use them at optimally at 60-90C as taught by R5.

### ***Response to Arguments***

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Applicants' arguments have been thoroughly reviewed. They are not deemed persuasive for the following reasons.

1. Regarding the Declaration by Mr. Dauvrin:

a. While the views expressed by Mr. Dauvrin are highly respected, attention is drawn to the following.

The disclosure by Klingenberg clearly states that gluten is weakened in the preparation of bakery products. This is clearly indicative of the incorporation of the protease in the dough prior to baking. If a hydrolysate of gluten was meant, incorporation of the hydrolysate rather than the weakening of gluten would have been expressed. In other words, the word "weakening " implies that the gluten in the dough is being addressed not a gluten hydrolysate in which "hydrolysis" should be addressed not weakening.

On the other hand, incorporation of protease and amylase into the dough prior to baking, to increase the shelf life of bread (retarding the staling) is an old and known process in the art.

1. Applicants argue that Klingenberg et al. (R1) neither teaches nor suggests that this thermitase is added to the dough prior to baking.

a. R1 teaches the method for producing the thermostable protease from the source as presently claimed. R1 discloses that Thermitase is used for gluten weakening in the production of processed foodstuff, waffles and bakery products.

As explained above, the word "weakening" implies that the enzyme is being added to the dough prior to baking.



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In the art of baking, the anti-staling compositions employ protease and amylase. The protease acts on the gluten component of the dough. The hydrolysis of gluten in coordination with starch hydrolysis will bring about the retardation of staling in bread and other baked products. The controlled partial break down of gluten will cause the softening of the bread crumb which in turn will help retard the staling of bread. However, starch retrogradation also plays an important role in staling of bread. The addition of amylase to the dough prior to baking is also known in the art for that matter.

2. Applicants argue that Although the Solpro 300 protease is added to a component of the bakery product (the flour), it is not added to the dough prior to baking and, in fact, would not be present in the dough since it would be denatured by pasteurization.

a. It should be realized that "Solpro 300" is a commercial gluten hydrolysate, not a protease. Please see paragraph 8 of the Declaration by Mr. Dauvrin.

3. Applicants argue that other gluten hydrolyzing enzymes such as papain and thermolysin are not able to retard staling when added to bakery products, therefore, it would not be expected that serine proteases would be able to retard staling and that thermostable serine proteases unexpectedly result in antistaling effect in bakery products when added to the dough to be baked.

a. Adding a protease and an amylase (involving proteins and starch) to bread dough is an old and known process in the art. Papain has also been implicated in retarding staling when added to the dough prior to baking bread.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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